

Louisiana Office of Public Health Laboratories	
Test Name	GSP Neonatal Biotinidase Kit Time Resolved Fluoroimmunoassay
PHL Location	Central Lab 1209 Leesville Avenue Baton Rouge, La. 70802
CPT Code	82261
Synonyms	Biotinidase
Brief Description of Test	This kit is intended for the quantitative in vitro determination of human biotinidase activity in blood specimens dried on filter paper as an aid in screening newborns for biotinidase deficiency using the GSP instrument.
Possible Results	Normal, Presumptive Positive
Reference Range	>50 u/dL = Normal ≤50 u/dL = Presumptive Positive
Specimen Type	Neonatal Dried Blood Spot
Specimen Container(s):	Standard manila envelopes can be used for shipping
Minimum volume accepted:	Minimum of two completely filled blood spot circles.
Collection Instructions	Blood specimens should be taken directly from a heel prick onto filter paper.
Storage and Transport Instructions	Allow the blood specimen to air-dry in a horizontal position for at least 3 hours at ambient temperature (+18 to +25 °C), not in direct light. Do not heat or stack the specimens during the drying process. Transport of mail the specimen to the laboratory within 24 hours after collection, unless otherwise directed by the screening laboratory.
Limitations of the Procedure	<p>Ampicillin (1.4 mg/dL and above), sulfisoxazole (7.5 mg/dL and above) at low biotinidase activity levels (35 U/dL) and ampicillin (2.8 mg/dL) at high biotinidase activity levels (150 U/dL) were found to interfere with this test by increasing measured biotinidase activity by 19.9%, 32.1% and 15.6%, respectively. Elevated ampicillin (2.8 mg/dL) and 13907242-1 (en) 19 sulfisoxazole (15 mg/dL) levels near the biotinidase cut-off did not exhibit a significant effect (&lt; 15%).</p> <p>Glutathione levels above normal (&gt; 30 mg/dL) can interfere with this test by increasing biotinidase activity by 16.1% or more. This could result in the misclassification of a patient with a biotinidase result near the cut-off value as 'normal' when in fact, the patient should be classified as 'deficient'.</p> <p>A patient with known or clinically suspected elevated blood glutathione concentration (&gt; 30 mg/dL) should be screened with an alternative method and confirmed according to local requirements for follow-up testing.</p>

	<p>Unconjugated bilirubin (10 mg/dL) added to whole blood at low biotinidase activity levels (35 U/dL) were found to interfere with this test by increasing measured biotinidase activity by 18.7%. Elevated unconjugated bilirubin level (20 mg/dL) near the biotinidase cut-off did not exhibit a significant effect (&lt; 15%).</p> <p>Conjugated bilirubin (2.5 mg/dL and above) and triglyceride (250 mg/dL and above) added to whole blood were found to interfere with this test by decreasing measured biotinidase activity by 26.0% and 15.7%, respectively. Elevated conjugated bilirubin (2.5 mg/dL and above) and triglyceride (250 mg/dL and above) levels may cause a false positive screening result for a specimen with measured biotinidase activity near the cut-off.</p>
Interfering Substances	<p>Ampicillin (1.4 mg/dL and above), sulfisoxazole (7.5 mg/dL and above) at low biotinidase activity levels (35 U/dL) and ampicillin (2.8 mg/dL) at high biotinidase activity levels (150 U/dL) were found to interfere with this test by increasing measured biotinidase activity by 19.9%, 32.1% and 15.6%, respectively. Elevated ampicillin (2.8 mg/dL) and 13907242-1 (en) 19 sulfisoxazole (15 mg/dL) levels near the biotinidase cut-off did not exhibit a significant effect (&lt; 15%).</p> <p>Glutathione levels above normal (&gt; 30 mg/dL) can interfere with this test by increasing biotinidase activity by 16.1% or more. This could result in the misclassification of a patient with a biotinidase result near the cut-off value as 'normal' when in fact, the patient should be classified as 'deficient'. A patient with known or clinically suspected elevated blood glutathione concentration (&gt; 30 mg/dL) should be screened with an alternative method and confirmed according to local requirements for follow-up testing.</p> <p>Unconjugated bilirubin (10 mg/dL) added to whole blood at low biotinidase activity levels (35 U/dL) were found to interfere with this test by increasing measured biotinidase activity by 18.7%. Elevated unconjugated bilirubin level (20 mg/dL) near the biotinidase cut-off did not exhibit a significant effect (&lt; 15%). Conjugated bilirubin (2.5 mg/dL and above) and triglyceride (250 mg/dL and above) added to whole blood were found to interfere with this test by decreasing measured biotinidase activity by 26.0% and 15.7%, respectively. Elevated conjugated bilirubin (2.5 mg/dL and above) and triglyceride (250 mg/dL and above) levels may cause a false positive screening result for a specimen with measured biotinidase activity near the cut-off.</p>

## References

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	<p>[11] Clinical and Laboratory Standards Institute (2003): Evaluation of Linearity of Quantitative Measurement Procedures; A Statistical Approach; Approved Guideline. CLSI document EP6-A. CLSI, Wayne, Pennsylvania 19087–1898, USA.</p> <p>[12] Clinical and Laboratory Standards Institute (2005): Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition. CLSI document EP7-A2. Clinical and Laboratory Standards Institute, Wayne, Pennsylvania 19087–1898, USA.</p>
Additional Information	NA
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